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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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Handwritten text, likely a date and time stamp, possibly indicating the filing date and time.

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
08/981,559

Applicant(s)
Wallach et al.

Examiner
David S. Romeo

Group Art Unit
1647



☒ Responsive to communication(s) filed on 30 Jun 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) 1-28 and 30-35 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 29 and 36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-36 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's election without traverse of group I, claims 28 and 35, in Paper No. 13 is acknowledged.

2. Upon further consideration the restriction requirement set forth in the Office action mailed
5 06/02/2000 (Paper No. 12) is withdrawn.

3. Newly submitted claims 28, 35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim(s) 28, 35 are drawn to a method of screening for compounds that mediate the shedding or proteolytic processing of TNF. The invention originally claimed, claim(s) 29, 36, are drawn to a method of screening for
10 compounds that modulate the phosphorylation of the intracellular domain of TNF. The inventions listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of claim(s) 28, 35 is the shedding or proteolytic processing of TNF. The special technical feature of the invention originally claimed is the phosphorylation of
15 the intracellular domain of TNF. Each performs different functions, using different starting materials and/or process steps and/or with different outcomes. There exist no special technical feature between the groups.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28 and 35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5 4. Claims 1-36 are pending. Claims 1-27, 30-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8. Claims 29 and 36 are being examined.

5. Any objection or rejection of record that is not maintained in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be
10 found in a prior Office action.

6. Claim 29 is rejected under 35 U.S.C. § 112, second paragraph, over the recitation of "capable of modulating" (line 4) because it is unclear whether such "modulating" actually occurs as part of the screening process or whether the molecule is merely capable of such "modulating" and some other type of screening process is intended. An element that is "capable of" performing
15 a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. The metes and bounds of the claim(s) are not

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clearly set forth. Applicants' arguments have been fully considered but they are not persuasive. Although the term "capable of modulating" is not per se indefinite, in the context of the present claim it is unclear whether such "modulating" actually occurs as part of the screening process or whether the molecule is merely capable of such "modulating" and some other type of screening process is intended. The examiner's focus in the rejection of the instant claim for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision. The examiner's focus is not whether more suitable language or modes of expression are available. If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. Since the claim does not set forth any steps in the screening process, and since the recitation of "capable of modulating" is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense, the metes and bounds of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty. Incorporating the limitations of claim 36 into claim 29 may overcome this rejection.

7. Claim 29 is rejected under 35 U.S.C. § 112, second paragraph, over the recitation of "directly or indirectly". The term "directly or indirectly" in claim 29 is a relative term which renders the claim indefinite. The term "directly or indirectly" is not defined by the claims, the

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specification does not provide a standard for ascertaining the requisite degree of "directness" or "indirectness", and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Applicants' arguments have been fully considered but they are not persuasive. It is noted that the features upon which applicant relies (i.e., "binds to ... the 26 kDa TNF" and "interaction with one or more effector proteins") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. It is suggested that the term "directly or indirectly" be deleted.

8. Claim 29 is rejected under 35 U.S.C. § 112, second paragraph. Claim 29 provides for the screening, identification, characterization, and production of a molecule, but, since the claim does not set forth any steps involved in the screening, identification, characterization, and production it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process without any active, positive steps delimiting how this process is actually practiced.

15 The rejection of record is applied to claim 36 over the identification, characterization, and production of a molecule.

Applicants' arguments have been fully considered but they are not persuasive. The claim does not set forth any steps involved in the screening, identification, characterization, and

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production it is unclear what method/process applicant is intending to encompass. It is noted that the features upon which applicant relies (i.e., "yeast two-hybrid procedure") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Incorporating the limitations of claim 36 into claim 29 may overcome this rejection with respect to "screening". It is suggested that the "identifying", "characterizing", and "producing" steps be eliminated.

Claim Rejections - 35 USC § 102

9. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Ohta (u9)¹.

Applicants' arguments have been fully considered but they are not persuasive. The claim does not set forth any steps in the screening process, and the recitation of "capable of modulating" is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. Ohta describes a process that encompasses all the claimed method steps. LPS is inherently capable of modulating the phosphorylation of the intracellular domain of TNF. Incorporating the limitations of claim 36 into claim 29 may overcome this rejection.

¹References cited by the examiner are in an alphanumeric format, such as "a1", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

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New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 101

10. Claim 36 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

5 The claim is drawn to or encompasses a method of screening for compounds that bind the intracellular domain of 26 kDa TNF and modulate the phosphorylation thereof. The specification teaches phosphorylation of the serine residues of the intracellular domain of 26 kDa TNF.

However, the biological significance of this phosphorylation is unknown. Evidence warranting further study is not equivalent to evidence showing the type of utility required by 35 U.S.C. 101.

10 Further experimentation is necessary to attribute a utility to the claimed screening process. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966) (noting that in context of the utility requirement "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

15 Claim 36 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37
10 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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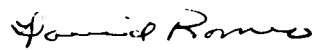
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


David Romeo
Primary Examiner
September 20, 2000